

| <b>Notice of Allowability</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|-------------------------------|------------------------|---------------------|--|
|                               | 09/827,255             | WONG ET AL.         |  |
|                               | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                               | J. D. Schultz, Ph.D.   | 1635                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to The Interview dated 20 June 2005.
2.  The allowed claim(s) is/are 1-7,9 and 11-13.
3.  The drawings filed on 05 April 2001 are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*
  - c)  None
 of the:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

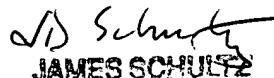
\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached  
 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
    - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of  
 Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
 Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
 of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
 Paper No./Mail Date 20 June 2005.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

  
**JAMES SCHULTZ**  
 PATENT EXAMINER

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### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on July 29, 2005, Michael Berger and Pamela Wong requested an extension of time for 1 MONTH(S) and authorized the Director to charge Deposit Account No. 13-0480 (atty. Docket number 32144183.1336) the required fee of \$60 (small entity) for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Pamela Wong and Michael Berger on 20 June 2005.

The application has been amended as follows, and is considered to comprise a complete listing of all pending claims:

1 (Currently amended). A composition for the targeted delivery of an active agent to a tissue expressing asialoglycoprotein receptors comprising ~~an effective amount of the said~~ agent encapsulated in a liposome having a molar ratio PC:Chol:PS of 11:42:0.025 11:4:0.025 coupled to desialylated glycoprotein-αL.

2 (Previously presented). The composition of claim 1, wherein the agent is a drug or polynucleotide.

3 (Previously presented). The composition of claim 2, wherein the polynucleotide is cDNA encoding a protein, a ribozyme, or antisense DNA.

4 (Previously presented). The composition of claim 1, wherein the agent is selected from the group consisting of cytotoxic drugs and proteins.

5 (Previously presented). The composition of claim 4, wherein the cytotoxic drug is selected from the group consisting of doxorubicin, vincristine, daunorubicin, and amphipathic amines.

6 (Currently amended). The composition of claim 1, wherein the desialylated glycoprotein- $\alpha$ 1 is coupled to the liposome by an avidin-biotin or thiol-maleamide linkage linkages.

7 (Currently amended). A method for targeted delivery of an active agent to a tissue expressing asialoglycoprotein receptors comprising ~~delivery delivering~~ to the tissue an effective amount of the composition of claims 1 or 6.

8 (Canceled).

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9. (Currently amended) A composition for the targeted delivery of an active agent to a tissue expressing asialoglycoprotein receptors comprising ~~an effective amount of a~~ doxorubicin encapsulated in a liposome having a molar ratio PC:Chol:PS of 11:0.025 11:4:0.025 coupled to desialylated glycoprotein- $\alpha$ 1 by an avidin-biotin linkage.

10. (Canceled).

11 (Currently amended). A method for targeted delivery of an active agent to a tissue expressing asialoglycoprotein receptors comprising ~~delivery delivering~~ to the tissue ~~an effective amount of~~ the composition of claim 1, whereby the agent is a polynucleotide or protein.

12 (Currently amended). A method for targeted delivery of an active agent to a tissue expressing asialoglycoprotein receptors comprising ~~delivery delivering~~ to the tissue ~~an effective amount of~~ the composition of claim ~~11~~ 2, whereby the polynucleotide is cDNA encoding a protein, a ribozyme, or antisense DNA.

13 (Currently amended). A method for targeted delivery of an active agent to a tissue expressing asialoglycoprotein receptors comprising ~~delivery delivering~~ to the tissue ~~an effective amount of~~ the composition of claim 1, whereby the agent is selected from the group consisting of doxorubicin, vincristine, daunorubicin, and amphipathic amines.

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### Conclusion

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

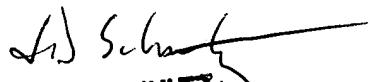
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JD Schultz, PhD

  
JAMES SCHULTZ  
PATENT EXAMINER